

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
NILS OVE GUSTAVSSON <i>et al.</i>)	Group Art Unit: Unassigned
)	
Application No.: Unassigned)	Examiner: Unassigned
)	
Filed: July 28, 2003)	Confirmation No.: Unassigned
)	
For: PHARMACEUTICALLY)	
ACCEPTABLE STARCH)	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56,
Applicants submit information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

This is a Divisional of Application No. 09/970,648, filed October 5, 2001.

Applicants request that the publications of record during the prosecution of parent
Application No. 09/970,648 be considered during the examination of the present
Application.

A copy of an International Search Report dated February 21, 2002 that was issued
in conjunction with International Application No. PCT/SE01/02163, filed October 5, 2001,
that corresponds to the present Application is attached.

Applicants further provide a form PTO-1449 that lists the publications of record during the prosecution of parent Application No. 09/970,648. Each of these publications should be available in the file of parent Application No. 09/970,648. Should the Examiner encounter difficulty in locating any of these items, please contact the undersigned attorney and a replacement copy will be promptly provided.

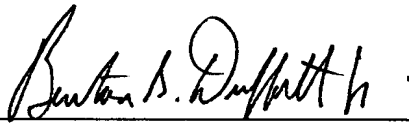
Publications listed on the form PTO-1449 include the items cited in the International Search Report, six (6) United States Patents cited by the Examiner during prosecution of the parent Application, and forty (40) publications from the technical literature many of which are discussed in Applicants' Specification.

The examination and allowance of the Application are respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: July 28, 2003

By: 
Benton S. Duffett, Jr.
Registration No. 22,030

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Substitute for forms 1449A/PTO & 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTORNEY'S DKT NO. 003301-072	APPLICATION NO. Unassigned
	APPLICANT NILS OVE GUSTAVSSON <i>et al.</i>	
	FILING DATE July 28, 2003	GROUP Unassigned

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	6,248,268B		Cook <i>et al.</i>	06/2001
	6,010,574A		Jeffcoat <i>et al.</i>	01/2000
	5,981,719		Woiszwilllo <i>et al.</i>	11/1999
	5,959,102A		Wasserman <i>et al.</i>	09/1999
	5,945,528		Klaus Sommermeyer <i>et al.</i>	08/1999
	5,849,884		Woiszwilllo <i>et al.</i>	12/1998
	5,776,885		Orsolini <i>et al.</i>	07/1998
	5,753,234		Lee <i>et al.</i>	05/1998
	5,667,808		Johnson <i>et al.</i>	09/1997
	5,654,010		Johnson <i>et al.</i>	08/1997
	5,622,657		Takeda <i>et al.</i>	04/1997
	5,578,709		Woiszwilllo <i>et al.</i>	11/1996
	5,470,582		Supersaxo <i>et al.</i>	11/1995
	5,455,342		Redding, Jr.	10/1995
	5,424,302		Ernst Nitsch	06/1995
	5,407,609		Tice <i>et al.</i>	04/1995
	5,319,046A		Kozulic <i>et al.</i>	06/1994
	4,713,249		Schröder	12/1987
	4,517,022A		Harvey	05/1985
	4,389,330		Tice <i>et al.</i>	06/1983
	3,909,288A		Powell <i>et al.</i>	09/1975
	3,881,991		Kurimotor <i>et al.</i>	05/1975
	3,737,337		Schnoring <i>et al.</i>	06/1973
	3,691,090		Kitajima <i>et al.</i>	09/1972

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes	Translation No
	EP 0 330 180	B2	Europe	03/1999		
	EP 0 688 429	B1	Europe	02/1998		
	EP 0 540 582	B1	Europe	08/1994		
	EP 0 213 303	A2	Europe	03/1987		
	EP 0 008 241	A2	Europe	02/1980		
	WO 99/20253	A1	International	04/1999		
	WO 99/00425	A1	International	01/1999		
	WO 97/14408	A1	International	04/1997		
	WO 96/10042	A1	International	04/1996		
	WO 94/12158	A1	International	06/1995		
	WO 93/21008	A1	International	10/1993		
	WO 90/13780	A1	International	11/1990		
	11302156		Japan	11/1999	X	

Substitute for forms 1449A/PTO & 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTORNEY'S DKT NO. 003301-072	APPLICATION NO. Unassigned
	APPLICANT NILS OVE GUSTAVSSON <i>et al.</i>	
	FILING DATE July 28, 2003	GROUP Unassigned

NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	"Formation and Isolation of Spherical Fine Protein Microparticles Through Lyophilization of Protein - Poly(ethylene glycol) Aqueous Mixture", Takahiro Morita et al., <i>Pharmaceutical Research</i> , Vol. 17, 11, 2000, Pages 1367 to 1373.
	Protein encapsulation into biodegradable microspheres by a novel S/O/W encapsulation method using poly(ethylene glycol) as a protein micronization adjuvant", Takahiro Morita et al., <i>Journal of Controlled Release</i> , 69 (2000) Pages 435-444.
	Artursson <i>et al.</i> , "Characterization of Polyacryl Starch Microparticles as Carriers for Proteins and Drugs," <i>Journal of Pharmaceutical Sciences</i> , Vol. 73, No. 11, pp. 1507-1513, (1984).
	Franssen <i>et al.</i> , "A Novel Preparation Method for Polymeric Microparticles Without the Use of Organic Solvents," <i>International Journal of Pharmaceutics</i> , Vol. 168, pp. 1-7 (1998).
	Fu <i>et al.</i> , "Visual Evidence of Acidic Environment Within Degrading Poly(lactic-co-glycolic acid) (PLGA) Microspheres" <i>Pharmaceutical Research</i> , Vol. 17, No. 1, pp. 100-106 (2000).
	Laakso <i>et al.</i> , "Biodegradable Microspheres IV: Factors Affecting the Distribution and Degradation of Polyacryl Starch Microparticles," <i>Journal of Pharmaceutical Sciences</i> , Vol. 75, No. 10, pp. 962-967 (1986).
	Laakso <i>et al.</i> , "Biodegradable Microspheres X: Some Properties of Polyacryl Starch Microparticles Prepared from Acrylic Acid-Esterified Starch," <i>Journal of Pharmaceutical Sciences</i> , Vol. 76, No. 12, pp. 935-939 (1987).
	Schröder, "Crystallized Carbohydrate Spheres as a Slow Release Matrix for Biologically Active Substances," <i>Biomaterials</i> , Vol. 5, pp. 100-104 (1984).
	Schröder, "Crystallized Carbohydrate Spheres for Slow Release and Targeting," <i>Enzymology</i> , Vol. 112, No. 9, pp. 116-128 (1985).
	Stenekes <i>et al.</i> , "The Preparation of Dextran Microspheres in an All-Aqueous System: Effect of the Formulation Parameters on Particle Characteristics," <i>Pharmaceutical Research</i> , Vol. 15, No. 4 pp. 557-561 (1998).
	Stjärnkvis <i>et al.</i> , "Biodegradable Microspheres XIII: Properties of the Crosslinking Chains in Polyacryl Starch Microparticles," <i>Journal of Pharmaceutical Sciences</i> , Vol. 78, No. 1, pp. 52-56 (1989).
	Agersø <i>et al.</i> , "Plasma Concentration of hGH and anti-hGH Antibodies After Subcutaneous Administration of hGH for 3 Weeks to Immunosuppressed Pigs," <i>J. Pharmacol Toxicol</i> No. 41 pp. 1-8 (1999).
	Johnson <i>et al.</i> , "A Month-Long effect From a Single Injection of Microencapsulated Human Growth Hormone," <i>Nature Medicine</i> , Vol. 2, No. 7 pp. 795-799 (1996).
	Putney, "Encapsulation of Proteins for Improved Delivery," <i>Current Opinion in Chemical Biology</i> , Nol. 2, pp. 548-552 (1998).
	"Clean Package Insert," Nutropin Depot (somatropin(rDNA origin) for injectable suspension), Genentech, Inc., 1 DNA Way, South San Francisco, CA 940-4990, pp. 1-6 (December 13, 1999).

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.